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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,149	04/16/2004	Michael A. Spohn	CV/04-002	8770

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EXAMINER

GILBERT, ANDREW M

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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11/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/826,149

Applicant(s)

SPOHN ET AL.

Examiner

Andrew M. Gilbert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-75 is/are pending in the application.
- 4a) Of the above claim(s) 1-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/14/2007 has been entered.

Acknowledgments

2. This office action is in response to the reply filed on 6/14/2007.
3. In the reply the Applicant amended claims 27, 42, and 60.
4. Additionally, the Applicant filed a Petition for Requirement for Restriction Under 37 C.F.R. 1.144 to rejoin claims 27-59. The Petition has been GRANTED because all limitations of the subcombination are found in the combination claims and thus a combination-subcombination restriction is improper. The restriction of claims 27-59 has hereby been withdrawn.

Election/Restrictions

5. Claims 27-59 have been rejoined pursuant to MPEP 821.04 in view of the applicant's arguments filed in the Petition filed on 6/14/2007.
6. Claims 1-26 remain withdrawn.
7. Thus, claims 27-75 are pending for examination.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 27-35, 38-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Holm (5746979). Holm discloses a connector, comprising: a first connector member (3; Fig 1-4) comprising an outer housing and a first threaded member (9) coaxially disposed in the outer housing and separated therefrom by an annular cavity (1 or 23; the Examiner notes that the Applicant has not structurally defined the annular cavity to preclude either of 1 or 23 from reading on the claim limitations; the Examiner strongly recommends further structurally defining the annular cavity); and a second connector member (2) comprising a second threaded member (11); wherein the first threaded member and second threaded member cooperate to securely and releasably connect the first member to the second member (Fig 1-4), and wherein the second threaded member is received in the outer housing of the first connector member when the first connector member is connected to the second connector member (Figs 1-4); wherein the first threaded member is recessed within the outer housing (8, 9, Figs 1-4); wherein the first threaded member is formed as an externally-threaded luer (8, 9, Figs 1-4); wherein the externally-threaded luer is recessed within the outer housing (8, 9, Figs 1-4); wherein the second member further comprises a luer disposed in the second threaded member and adapted to cooperate with the first threaded member (10, 11,

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Figs 1-4); wherein the luer is recessed within the second threaded member (10, 11, Figs 1-4); wherein the first threaded member is formed as an externally-threaded female luer and the second member further comprises a male luer disposed in the second threaded member (Figs 1-4), such that the male luer cooperates with the female luer when the first connector member is connected to the second connector member (Figs 1-4); wherein at least one of the female luer and the male luer are recessed within the outer housing and the second threaded member (Figs 1-4), respectively; wherein the first threaded member is externally-threaded (8, 9, Figs 1-4) and the second threaded member is internally-threaded (10, 11, Figs 1-4); wherein the second threaded member comprises at least one circumferentially-extending raised structure (12) on an external surface thereof, the raised structure defining a tortuous path with an inner wall of the outer housing for inhibiting liquid flow between the outer housing and the second threaded member when the first connector member is connected to the second connector member (12, 6, Figs 1-4; the Examiner recommends further structurally defining this aspect of the Applicant's invention to overcome the prior art); wherein the raised structure defines a chamber with the inner wall of the outer housing and the first threaded member when the first connector member is connected to the second connector member (12, 6, 10, Figs 1-4).

10. Claims 27-39, 42-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Morimoto et al (6224568). Morimoto et al discloses a connector (13), comprising: a first connector member (41; Fig 13, 15, 20) comprising an outer housing and a first threaded

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member (41, 43; Fig 13, 15, 20) coaxially disposed in the outer housing and separated therefrom by an annular cavity (41; Fig 13, 15, 20); and a second connector member (4; Fig 13, 15, 20) comprising a second threaded member (4a; Fig 13, 15, 20); wherein the first threaded member and second threaded member cooperate to securely and releasably connect the first member to the second member, and wherein the second threaded member is received in the outer housing of the first connector member when the first connector member is connected to the second connector member (Fig 13, 15, 20); wherein the first threaded member is recessed within the outer housing (41, 43, Fig 13, 15, 20); wherein the first threaded member is formed as an externally-threaded luer (41, 43, Fig 13, 15, 20); wherein the externally-threaded luer is recessed within the outer housing (Fig 13, 15, 20); wherein the second member further comprises a luer disposed in the second threaded member and adapted to cooperate with the first threaded member (4, 4a; Fig 13, 15, 20); wherein the luer is recessed within the second threaded member (4, 4a; Fig 13, 15, 20); wherein the first threaded member is formed as an externally-threaded female luer and the second member further comprises a male luer disposed in the second threaded member (Fig 13, 15, 20), such that the male luer cooperates with the female luer when the first connector member is connected to the second connector member (Fig 13, 15, 20); wherein at least one of the female luer and the male luer are recessed within the outer housing and the second threaded member (Fig 13, 15, 20), respectively; wherein the first threaded member is externally-threaded (41, 43, Fig 13, 15, 20) and the second threaded member is internally-threaded (4, 4a; Fig 13, 15, 20); wherein the second threaded member comprises at least one

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circumferentially-extending raised structure (external flange of 4 that contacts 41; Fig 13, 15, 20) on an external surface thereof, the raised structure defining a tortuous path with an inner wall of the outer housing for inhibiting liquid flow between the outer housing and the second threaded member when the first connector member is connected to the second connector member (external flange of 4 that contacts 41; Fig 13, 15, 20); wherein the raised structure defines a chamber with the inner wall of the outer housing and the first threaded member when the first connector member is connected to the second connector member (see chamber formed in Fig 13, 15, 20); wherein the reservoir and syringe barrel act as a fluid path set for use in a fluid delivery system via the syringe and comprises a first section (5) and a second section (1).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holm in view of Raines et al (561268). Holm discloses the invention substantially as claimed except for expressly disclosing a cap having a groove associated with a raised rib of at least one of the first and second connector members. Raines et al teaches that it is known to have a cap with a groove (21, 66, 16) for a connector member for the purpose of protecting the infusion port and connector prior to use. It would have been obvious to one having ordinary skill in the art at the time the invention was made to

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modify the device as taught by Holm with the protective cap as taught by Raines et al for the purpose of protecting the infusion port and connector prior to use.

13. Claims 40-41, 55-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morimoto et al in view of Raines et al (561268). Morimoto et al discloses the invention substantially as claimed except for expressly disclosing a cap having a groove associated with a raised rib of at least one of the first and second connector members. Raines et al teaches that it is known to have a cap with a groove (21, 66, 16) for a connector member for the purpose of protecting the infusion port and connector prior to use. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Morimoto et al with the protective cap as taught by Raines et al for the purpose of protecting the infusion port and connector prior to use.

14. Claims 27-39, 42-54, 57-69, 72-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trombley, III et al (6096011) in view of Morimoto et al. Trombley, III et al discloses an injector system comprising: a source of injection fluid (505); a pump device (350); a fluid path set (Fig 6A-B) disposed between the source of injection fluid and the pump device, and comprising a first section (420) and a second section (510); and at least one connector (Fig 2-5) providing the removable fluid communication between the first section and the second section, the connector comprising: a first connector member (155) associated with one of the first section and the second section and comprising an outer housing (172) and a first threaded member (172) disposed in

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the outer housing; and a second connector member (175) associated with the other of the first section and the second section and comprising a second threaded member (192); wherein the first threaded member and second threaded member cooperate to securely and releasably connect the first member to the second member to establish the removable fluid communication between the first section and the second section (Figs 1-6b; col 5, lns 38-45), and wherein the second threaded member is received in the outer housing of the first connector member when the first connector member is connected to the second connector member (Fig 5); as to claims 57-59 and 73-75, see (Fig 6A, B; wherein the drip chamber has a projection, or spike 520; 400; col 6, lns 18-34; and 194 and proximal edge portion of 155 (ie corners closest to reference number 166) in Fig 4).

15. However, Trombley, III et al does not expressly disclosing a connector having a first connector member having an first threaded member separated therefrom by an annular cavity.

16. Morimoto et al teaches that it is known to have a connector (13) having a first connector member (41) having a first threaded member (41, 43) separated therefrom by an annular cavity (41) for the purpose of providing a shield between the sealing members (14, 41) of first and second connectors and the external environment helping to maintain sterility during storage or use. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the first connector as taught by Trombley, III et al with the first connector being separated therefrom by an annular cavity as taught by Morimoto et al for the purpose of providing a shield between

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the sealing members (14, 41) of first and second connectors and the external environment helping to maintain sterility during storage or use.

17. Claims 40-41, 55-56, and 70-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trombley, III et al in view of Morimoto et al in view of Raines et al. Trombley, III et al and Morimoto et al disclose the invention substantially as claimed except for expressly disclosing a cap having a groove associated with a raised rib of at least one of the first and second connector members. Raines et al teaches that it is known to have a cap with a groove (21, 66, 16) for a connector member for the purpose of protecting the infusion port and connector prior to use. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Trombley, III et al and Morimoto et al with the protective cap as taught by Raines et al for the purpose of protecting the infusion port and connector prior to use.

Response to Arguments

18. Applicant's arguments with respect to claims 60-75 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 5176415, 4526572, 7198611, 4225162.

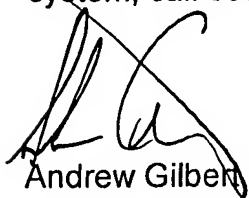
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571)

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272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

